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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/114,844	07/14/1998	AVI J. ASHKENAZI	1129R1	9726

7590

05/06/2002

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EXAMINER

KAUFMAN, CLAIRE M

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 05/06/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/114,844

Applicant(s)

ASHKENAZI ET AL.

Examiner

Claire M. Kaufman

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-14, 29, 35 and 38-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14, 29, 34, 35 and 38-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>25</u> . | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

The amendment filed 1/31/02 has been entered.

#### ***Response to Arguments***

The rejection of claims under 35 USC 112, second paragraph, is withdrawn in view of the amendment to the claims.

The rejection of claims 8 and 9 under 35 USC 112, first paragraph, is withdrawn in view of the amendment to the claims.

The rejection of claims 1-3, 6, 40 and 42-49 under 35 USC 112, first paragraph, is withdrawn in view of the amendment to the claims and upon reconsideration by the Examiner.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Interpretation***

In claim 40, section (c), it appears to have been Applicants' intention to have the binding property limit the fragment instead of the polypeptide of (a) or (b), though the claim is ambiguous. Because of the amendments made to other claims and because of Applicants' arguments, in order to overcome the rejection under 35 USC 112, first paragraph, and in the interest of compact prosecution, the Examiner is interpreting the claim such that the fragment of (c) binds Apo-2 ligand. If this is not Applicant's intended meaning, the claim would remain subject to the rejection under 35 USC 112, first paragraph, as set forth in the previous Office action beginning on page 4. Should Applicant disagree with the Examiner's interpretation of the claim, reinstatement of the rejection for claim 40 and dependent claims would not constitute a new grounds of rejection in the next Office action.

#### ***Claim Objections***

Claims 48 and 58 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must refer to claims in the alternative. See MPEP § 608.01(n). The claims depend both on the nucleic acid of claim 40 and on the polypeptide of claim 1 or 6.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 40 and dependent claims 7-14, 29, 34, 35, 41-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is indefinite because it recites the limitation "of the sequence of (a)" in line 3. It is unclear if this means (i) amino acid residues 56-212 of SEQ ID NO:1 or (ii) SEQ ID NO:1.

Claim 40 is indefinite because in part (c) is unclear if the fragment or the polypeptide of (a) or (b) has the property of binding Apo-2 ligand. This rejection could be obviated by specifying that "said fragment binds Apo-2 ligand" if appropriate.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40, 42-48, 51 and 58 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Part (c) of claim 40 includes a nucleic acid comprising a polynucleotide encoding a fragment of a polypeptide comprising amino acid residues 1-386 or 56-212 of SEQ ID NO:1 and wherein said fragment binds Apo-2 ligand (see rejection under 35 USC 112, second paragraph, above and ***Claim Interpretation*** section above). This means that the polypeptide fragment must bind the ligand but is not required to bind by means of a fragment of amino acids 56-212 or 1-386 of SEQ ID NO:1. The claim is silent as to what the polypeptide of (a) or (b) comprises besides the specified residues, but within the reasonable scope is amino acid residues of other proteins which are sufficient to bind Apo-2 ligand. Therefore, the fragment may consist of a

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portion of the polypeptide that is not residues 56-212 or 1-386 of SEQ ID NO:1, but instead is another unspecified portion of another protein which has the required binding property. A fragment of amino acids 56-212 or 1-386 of SEQ ID NO:1 which binds Apo-2 ligand meets the written description provision of 35 USC 112, first paragraph; however, a fragment of a protein with different amino acids which binds Apo-2 ligand does not.

### *Claim Rejections - 35 USC § 102*

Claims 1-6, 8-14, 29, 38-45, 47-55, 57 and 58 remain rejected under 35 U.S.C. 102(e) as being anticipated by Ni et al. (US Patent 6,124,580) for the reasons set forth in the previous Office action on page 6.

Applicants argue that the first priority document of Ni et al. has solely prophetic function, utility and binding properties of TR10, nor was TR10 actually expressed or tested. The argument has been fully considered, but is not persuasive. Ni et al. say in priority application 60/050,936 (p. 41, line 9, and p. 10, lines 13-14) that TRAIL (*a.k.a.* Apo-2 ligand) is a ligand of TR10. This statement, which is correct, is sufficient for enablement and utility for TR10. There is no requirement for enablement of utility that a product being claimed actually be tested for the functional property it is stated to have and upon which property satisfaction of enablement and utility are based, such that with the property enables the skilled artisan to use the claimed invention. According to MPEP 2164.02:

Compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed. An example may be "working" or "prophetic." A working example is based on work actually performed. A prophetic example describes an embodiment of the invention based on predicted results rather than work actually conducted or results actually achieved.

An applicant need not have actually reduced the invention to practice prior to filing. In *Gould v. Quigg*, 822 F.2d 1074, 1078, 3 USPQ 2d 1302, 1304 (Fed. Cir. 1987), as of Gould's filing date, no person had built a light amplifier or measured a population inversion in a gas discharge. The Court held that "The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it." 822 F.2d at 1078, 3 USPQ2d at 1304 (quoting *In re Chilowsky*, 229 F.2d 457, 461, 108 USPQ 321, 325 (CCPA 1956)). The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in

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the art will be able to practice it without an undue amount of experimentation. In re Borkowski, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970).

Therefore, even though the function of TR10 in provisional application 60/050,936 of Ni et al. is prophetic, it is correct and can be used by one of ordinary skill in the art to practice the claimed invention without undue experimentation.

Applicants argue on page 9 of the response that Ni et al. teach that the "effects of TNF family ligands and receptors are varied...", indicating that one could not reasonably have predicted the function or activity of TR10. The argument has been fully considered, but is not persuasive. Because the earliest priority document of Ni et al. gave an enabling use for TR10, binding TRAIL, predictability of other properties is not an issue.

Applicants argue that the activity of induction of apoptosis attributed to TR10 in 60/050,936 of Ni et al. is wrong, and therefore the Ni et al. do not deserve benefit of priority because of lack of disclosed actual function and activity. The argument has been fully considered, but is not persuasive. Even though it was later shown that TR10 inhibits apoptosis instead of stimulates it, the activity of binding to TRAIL, even though prophetic, is sufficient for enablement and utility. Although, not all prophetic uses of TR10 were correct, one was correct and that is all that is required.

### ***Claim Rejections - 35 USC § 103***

Claims 1-14, 29, 34, 35 and 38-58 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ni et al. (US Patent 6,124,580) for the reasons set forth in the previous Office action on page 7.

Applicants' argument directed to the rejection under 35 USC 102(e) also pertinent to the rejection under 103(a). These arguments have been addressed above.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Thursday from 8:30AM to 12:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (703) 308-6564.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. **NOTE:** If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office. **Please** advise the examiner at the telephone number above before facsimile transmission.

Claire M. Kaufman, Ph.D.



Patent Examiner, Art Unit 1646

May 2, 2002



**LORRAINE SPECTOR**  
**PRIMARY EXAMINER**